K072583

MAQUET

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Katrin Schwenkglenks Phone: +49 7478 921-151 Fax: +49 7478 921-400 E-mail: katrin.schwenkglenks@maquet-cp.com
Date Prepared:	September 07, 2007
Device Trade Name:	Plegiox Cardioplegia Heat Exchanger with and without Safeline Coating
Common/Usual Name:	Cardioplegia Heat Exchanger
Classification Names:	Cardiopulmonary Bypass Heat Exchanger (21 CFR 870.4240, product code: DTR)
Predicate Devices:	CSC 14 Blood Cardioplegia System, Cobe Cardiovascular Inc. (K012898) and Jostra RotaFlow Centrifugal Pump with Safeline Coating (K061072), Maquet Cardiopulmonary AG.

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Device Description
The Plegiox is a product, which is delivered to the end user in a pyrogen-free and sterile way. The product is determined for single use only. Re-sterilization and re-use are forbidden. The Plegiox is a cardioplegia heat exchanger with integrated bubble trap.

Statement of Indications for Use
The Plegiox heat exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.
The product is designed for single use only, for an application period of no longer than 6 hours.

Statement of Technical Characteristics Comparison
Maquet Cardiopulmonary AG has compared indications for use, design, specifications, performance characteristics and safety of the Plegiox Heat Exchanger with and without Safeline Coating and of the predicate devices.

In-vitro testing on safety and effectiveness was executed to demonstrate that the Plegiox with and without Safeline Coating described in this submission is substantially equivalent to the named predicate devices.

Indications for use for the Plegiox Cardioplegia Heat Exchanger, Maquet Cardiopulmonary AG:
"The Plegiox heat exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.
The product is designed for single use only, for an application period of no longer than 6 hours.

CSC 14 Cardioplegia Heat Exchanger, Cobe Cardiovascular Inc.:
"CSC14 is recommended for use as a heating/cooling device and bubble trap for cardioplegia and clear fluid perfusion in extracorporeal circulation associated with cardiopulmonary bypass. It is suggested not to use CSC 14 for more than 6 hours.
CSC 14 can be used in combination with the devices listed in paragraph 1. Devices which can be used with CSC 14."

Safeline Coating:
The Safeline Coating applied to the Plegiox Cardioplegia Heat Exchanger has the same intended use as the predicate RotaFlow Centrifugal Pump with Safeline Coating from Maquet Cardiopulmonary. The indications for use of the Safeline Coating is "To reduce the surface tension on blood contact surfaces." for both devices.

Comparison of the performance
The substantial equivalence in performance of the Plegiox Cardioplegia Heat Exchanger with the predicate device has been shown by in-vitro testing. The Plegiox Cardioplegia Heat Exchanger has shown to be as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K072583
Plegiox Cardioplegia Heat exchanger with and without Safeline
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger
Regulatory Class: Class II (two)
Product Code: DTR
Dated: March 14, 2008
Received: March 19, 2008

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072583

Device Name: Plegiox Cardiplegia Heat Exchanger with and without Safeline Coating

Indications for Use:

The Plegiox heat exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.
The product is designed for single use only, for an application period of no longer than 6 hours.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Jackson

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072583

(Posted November 13, 2003)